



UNIVERSITY OF  
SOUTH DAKOTA

Human Subjects Protection Program

## Clarification Regarding Pilot Studies and Research Development

**If I am conducting a pilot study or developing my research do I need human subject approval? I will be interacting with people but I won't be collecting data.**

Pilot projects are preliminary investigations performed to determine if a study is feasible. The purpose is to refine data collection procedures and research design on a small scale.

The steps taken in research development or in the conduct of a pilot study usually are not intended to contribute to generalizable knowledge. The data gathered typically isn't for analysis purposes and as such do not qualify as research and do not need human subject approval.

### **Exceptions that require human subject approval PRIOR to the start of the pilot project:**

- Members from a vulnerable population are participants
- Methods with more than minimal risk are utilized
- Collection of sensitive data
- The possibility exists that the collected data will be used in some form or another for publication purposes

As always, please call, email, or stop by the Office of Human Subject Protection any time with questions or concerns.

We're always happy to help!